UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	**Criminal No.: 09-CR-10035-DPW**
v.	)	
SHANE DOYLE,	)	
Defendant.	)	

GOVERNMENT'S MOTION FOR
DOWNWARD DEPARTURE BASED ON SUBSTANTIAL ASSISTANCE

The United States respectfully moves the Court, pursuant to United States Sentencing Guideline ("U.S.S.G.") §5K1.1, for a downward departure in defendant Shane Doyle's sentence based on his substantial assistance. In support of this motion, the United States asserts the following:

1. On April 14, 2009, the defendant, Shane Doyle ("Doyle"), waived indictment and pled guilty to an Information charging one count of felony misbranding in violation of 21 U.S.C. §§331(a), 333(a)(2) and 352. On April 2, 2009, the United States had filed a plea and cooperation agreement, which included a guideline calculation.[1] The plea agreement also

[1]The guideline calculations from the plea agreement are in accord with those in the Presentence Report and are set forth below:

base offense level (U.S.S.G. §2N2.1(c)(1) cross referencing §2B1.1)	6
+	
loss enhancement (U.S.S.G. §2B1.1(b)(1)(C))	4
+	
reckless risk of serious bodily harm (U.S.S.G. §2B1.1(b)(13)(A))	4
-	
acceptance of responsibility (U.S.S.G. §3E1.1)	2
Total Offense Level =	12
Advisory Guideline Range for CHC I =	10-16 months (Zone C)

incorporates by reference a Civil Settlement Agreement whereby Doyle agreed to pay (and has paid) to the United States the sum of $75,000 in recognition of his falsification of Institutional Review Board approvals, which were required by law in order to sell medical devices known as OP-1 Putty and OP-1 Implant.

2. The criminal charge arose from Doyle's conduct when he was employed as a territory manager for Stryker Biotech, LLC ("Stryker Biotech"), a medical device company based in Hopkinton, Massachusetts, which manufactured and sold medical devices for implantation, during invasive surgeries, to aid in healing of fractured or broken bones. In 2007, Doyle was responsible for promoting Stryker Biotech's products in Arizona and New Mexico. See Presentence Report ¶9. The products were known then as OP-1 Putty, OP-1 Implant (hereinafter, the "OP-1 products" or "OP-1") and Calstrux. Id. at ¶¶9-10. These products were regulated by the United States Food and Drug Administration ("FDA") and had been accorded specific exemptions/approvals by the FDA. The OP-1 products had both been accorded a Humanitarian Device Exemption by the FDA, see 21 U.S.C. §360j(m), and were approved for specific uses in very limited patient populations. Presentence Report ¶¶10-11.

The OP-1 products were designed to promote bone growth. Calstrux, on the other hand, was a bone void filler, approved by the FDA under a Section 510(k) premarket notification of intent. Stryker Biotech never applied to the FDA for any combined use of OP-1 and Calstrux, nor did the FDA ever approve any such combined use. Presentence Report ¶13. However, in 2007, Doyle promoted the sale and use of OP-1 with Calstrux, even though this was not an FDA-approved use. Id. Prior to promoting a mixture of OP-1 and Calstrux, Doyle knew that: (1) the products were not FDA-approved for combined use; (2) that there had been no randomized, well-

controlled trials to support a combined use of the two products; and (3) there had been reports of adverse events in some patients in whom a mixture of OP-1 and Calstrux had been implanted, including reports of infection, drainage and product migration. Id. at ¶15. However, Stryker Biotech encouraged its sales force to promote a combination of Calstrux with OP-1 in order to respond to competitive pressures in the marketplace, such as the small quantity and poor handling quality of OP-1 on its own.

One of the means by which Doyle promoted this unapproved combined use was by preparing and distributing mixing instructions to surgeons, surgical staff and colleagues, sometimes advising surgical staff that particular mixing instructions "could be printed out and put in the fridge with the OP-1 to make sure there are no questions on how to mix." One set of mixing instructions used by Doyle was a so-called "dry-mix" and directed the user to combine all of the dry powder from the OP-1 and Calstrux then add only the amount of saline directed by the Calstrux.[2] Presentence Report ¶14. On May 16, 2007, Mr. Doyle provided these instructions in writing to a surgeon in New Mexico. See id. These mixing instruction documents constituted labeling of the two products, and the labeling was false or misleading because neither OP-1 nor Calstrux was approved by the FDA for combined use.

3. The crime that Doyle stands convicted of, misbranding of a medical device, specifically by promoting a mixture of OP-1 Putty and Calstrux that had not been clinically tested and had not been FDA approved for combined use, is a serious one in that it raises public health concerns and undermines the FDA's authority to regulate the sale and promotion of

[2]Calstrux and the OP-1 products came as dry powders and they each had to be constituted with a certain amount of saline as directed by their respective labels.

medical devices. However, after pleading guilty, Doyle has provided substantial assistance to the United States during its further investigation and prosecutions of illegal promotional conduct by Stryker Biotech and its current and former employees. Doyle has met with government attorneys and agents on a number of occasions and has provided information and documents to the government which have assisted in its investigation. The sentence recommended by the United States attempts to harmonize the dual aims of punishing the serious crime committed by Doyle, while crediting the substantial assistance he has provided to the United States during its investigation of his former employer, Stryker Biotech, and certain of his former Stryker Biotech colleagues.[3]

4. According to the calculations in the Presentence Report, Doyle's total offense level is 12 and his criminal history category is I, yielding a sentencing range of 10-16 months of imprisonment (Zone C). The United States now moves the Court, pursuant to U.S.S.G. §5K1.1, to depart downwards from the applicable guidelines range in view of Doyle's substantial assistance in the prosecution of others. Specifically, the government recommends that the Court impose the following sentence:

- 2 years probation, the first 7 months of which shall be served in home

[3]Since Doyle's guilty plea and the beginning of his cooperation with the government, another former Stryker Biotech territory manager also pled guilty (on May 7, 2009) to felony misbranding arising from the promotion of a combination of Calstrux and OP-1. United States v. Ring, 09-CR-10096-MLW. In addition, on October 28, 2009, a grand jury in this district returned a multi-count Indictment against Doyle's former employer, Stryker Biotech, LLC, and its former president, Mark Philip, and three of its current sales managers, William Heppner, David Ard (who was Doyle's direct manager for approximately two years) and Jeffrey Whitaker. United States v. Stryker Biotech, LLC, et als., 09-CR-10330-GAO. Among other counts, the Indictment charges a wire fraud scheme by all the defendants to defraud health care professionals through, among other things, promotion of a mixture of Calstrux and OP-1.

confinement;

- fine of $10,000; and
- mandatory special assessment of $100.

As set forth below, the government's recommendation is within the applicable guideline range (as reduced to a Zone B sentence in accordance with the government's motion under U.S.S.G. §5K1.1) and is consonant with the factors of 18 U.S.C. §3553, in that it, among other things, reflects both the nature and seriousness of the offense, as well as the history and characteristics of the defendant, which include his cooperation and substantial assistance in a significant (and now ongoing) criminal health care fraud prosecution.

Respectfully submitted,

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Certificate of Service

I hereby certify that the foregoing documents filed through the ECF system will be sent electronically to counsel for the defendant who is a registered participant as identified on the Notice of Electronic Filing (NEF), and that one copy will be delivered by messenger to USPO Martha Victoria.

/s/Jeremy M. Sternberg
Jeremy M. Sternberg
Assistant U.S. Attorney

Dated: December 24, 2009